REMARKS

At the time of the last Office Action claims 1-28 were present in the application. Of those claims, claims 1, 14, 19, 21, 23, 24, 26, 27 and 28 were independent claims.

In the last Office Action all of the previous rejections on prior art were withdrawn but the following new rejections were stated:

1. Claims 1, 4-6, 14-17, 19-21, 23-24 and 28 were rejected as lacking novelty under 35 U.S.C. §102(b) over GURUWAIYA et al. (6,251,136), newly cited;
2. Claims 2, 3, 7, 10, 11-13, 18, 22 and 25 were rejected as obvious under 35 U.S.C. §103(a) over GURUWAIYA et al. in view of EDER et al. (5,980,550), newly cited; and
3. Claims 8 and 9 were rejected as obvious under 35 U.S.C. §103(a) over GURUWAIYA et al. in view of SNYDER et al. (5,658,308), newly cited.

All of the method claims 26 and 27 were indicated to be allowable.

Applicants wish to thank Examiner Aamer Ahmed for the courteous and productive interview with applicants' undersigned counsel at the Patent and Trademark Office on July 26, 2006.

As discussed during the interview, vascular occlusive embolic coils having a thrombogenic agent thereon have been employed in the past to promote clotting in the treatment of vascular aneurysms. Such prior coils with the thrombogenic agent thereon have been coated with a protective coating or barrier of a water soluble agent which dissolves through contact with bodily fluids after placement at the aneurysm. The disadvantage of these coils is that there is no control as to when the dissolution of the protective coating begins and the thrombogenic agent is activated because the dissolution

is the result of the action of the blood on the coating. Thus, dissolution of the protective coating and exposure of the bioactive agent may commence upon introduction of the coils to the blood vessel and before it is placed at the aneurysm with obviously dire consequences.

The present invention is directed to such embolic coils comprising a support member 12 with a bioactive agent thereon, for example a thrombogenic agent such as polyglycolic acid, and upon which an outer barrier or protective coating 22, such as ethylene vinyl alcohol, is coated which is inert to bodily fluids or blood. Thus, dissolution of the barrier 22 will not take place when simply exposed to the bodily fluids. In the present invention, dissolution of the inert protective barrier 22 is accomplished by the introduction of an external fluid agent once the embolic coils have been placed as desired relative to the aneurysm. The external fluid agent is typically introduced through the placement catheter. In the alternative dissolution of the barrier may also be accomplished by heat or lazer after placement.

All of the independent claims, with the exception of the prior independent method claims 26, 27 and new claim 29, have been amended as discussed during the interview to set forth that the bioactive agent is a "**thrombus inducing** bioactive agent."

GURUWAIYA et al. discloses a stent 16 having a base coat 18 thereon, a pharmacological agent 20 on the base coat 18, and a third layer in the form of a continuous membrane 22 which encapsulates the entire device. The pharmacological agent 20 is in the form of dry micronized particles that readily adhere to the sticky base coat 18. Pharmacological agents disclosed by GURUWAIYA et al. include antibiotics, **anti-thrombotic** and anti-restenotic drugs. (col. 3, line 66 – col. 4, line 5). GURUWAIYA et al. contains no disclosure or suggestion that the pharmacological agent

20 should or could be a "thrombus inducing bioactive agent" as in the present claimed invention and, indeed, actually teaches the exact opposite, i.e. that it may be an **anti-thrombotic** drug. (See col. 4, lines 4-5).

GURUWAIYA et al. does disclose that the continuous membrane 22 which encapsulates the entire device may be ethylene vinyl alcohol as in the present invention. (col. 4, lines 32-36). However, of significance is that GURUWAIYA et al. selects this membrane material so that it is to be left on the stent after the stent is placed in its working position and the material is permeable to the pharmacological agent to permit the slow diffusion over the long term of the pharmacological agent therethrough. (col 2, lines 20-48, col. 4, lines 25-27, and col. 5, lines 15-18).

Thus, in summary, GURUWAIYA et al. fails to disclose or suggest that the pharmacological agent should be a "thrombus inducing bioactive agent" or, that the continuous encapsulating member 22 might or should be dissolved. Indeed, the diffusion of the pharmacological agent as contemplated by GURUWAIYA et al. through the encapsulating membrane 22 is much to slow for a "thrombus inducing bioactive agent" as in the present claimed invention. By its very nature, a thrombus inducing bioactive agent is intended to act immediately and completely after its placement in contrast to the pharmacological agents contemplated by GURUWAIYA et al. which are intended to be slow release by defusing slowly and over a long period of time to produce their desired result. Thus, the slow diffusion system contemplated by GURUWAIYA et al. would not be functional with the thrombus inducing bioactive agents as in the present claimed invention which require a large surface area of exposure to act instantaneously and quickly. Moreover, it is not clear that the thrombus inducing agents as claimed are even capable of diffusing through the membrane 22 of GURUWAIYA et al.

EDER et al. discloses a occlusive bioactive device comprising a helical support coil 202, an inner coating 204 which is permanently bound to the coil 202 which will produce thrombogenicity of the coil (col. 4, lines 57-61), and an outer coating 206. Unlike either GURUWAIYA et al. in which the outer coating is inert to bodily fluid and is intended to remain on the device over an extended period of time of use, or the present invention in which the outer barrier is inert to bodily fluid and is only dissolved when exposed to an external fluid agent, EDER et al. expressly discloses that the outer coating 206 is water soluble and dissolves by exposure to bodily fluid shortly after the occlusive member is deployed. (See col. 3, lines 14-15, and 40-43 and col. 7, lines 14-15). Thus, EDER et al. discloses nothing more than that which the invention is an express improvement upon, i.e. the relatively uncontrollable embolic device barrier coatings which dissolve when exposed to bodily fluids before their desired placement.

Accordingly, one skilled in the art would certainly not consider the modification of GURUWAIYA et al. by the teachings of EDER et al. Contrary to GURUWAIYA et al. which desires a permanent inert barrier which is not to be dissolved and which is intended to produce a slow diffusion of a nonthrombus inducing agent through the membrane, EDER et al. contemplates a rapid barrier dissolution when exposed to bodily fluids. To combine this prior art would destroy the intent and purpose of each of the respective references. Moreover, even if GURUWAIYA et al. is modified by the teachings of EDER et al., a vascular occlusive device still does not result in which premature dissolution of the barrier before the device is properly placed is avoided, but which is rapidly triggered to produce immediate thrombus inducing action only after the device is in its desired position as in the present invention.

SNYDER et al. simply discloses that a thrombogenic material 12 may be a polyglycolic acid. However, in SNYDER et al. the thrombogenic material 12 extends axially through the helical coil 13, and the thrombogenic material 12 is not coated at all therefore exposing the thrombogenic material immediately to reaction with bodily fluids unlike the device of the present invention.

Method claims 26 and 27 have been indicated to be allowable. New independent claim 29 is also a method claim which is a broadened version of allowed claim 27. It is respectfully submitted that new claim 29 should also be allowable as are the other method claims 26 and 27 because none of the prior art currently of record discloses or suggests the delivery of an external agent through a catheter to activate a barrier to expose a bioactive surface to bodily tissue.

For the above reasons, it is respectfully submitted that all of the claims in the present application, claims 1-29, are in condition for allowance. Accordingly, favorable reconsideration and allowance are requested.

Respectfully submitted,

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